

**§ 219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.**

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

**§ 219.121 [Reserved]**

**§ 219.122 Use of Federal funds.**

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

**§ 219.123 Early termination of research support: Evaluation of applications and proposals.**

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the

scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

**§ 219.124 Conditions.**

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

**PART 220—COLLECTION FROM THIRD PARTY PAYERS OF REASONABLE CHARGES FOR HEALTHCARE SERVICES**

**Sec.**

- 220.1 Purpose and applicability.
- 220.2 Statutory obligation of third party payer to pay.
- 220.3 Exclusions impermissible.
- 220.4 Reasonable terms and conditions of health plan permissible.
- 220.5 Records available.
- 220.6 Certain payers excluded.
- 220.7 Remedies and procedures.
- 220.8 Reasonable charges.
- 220.9 Rights and obligations of beneficiaries.
- 220.10 Special rules for Medicare supplemental plans.
- 220.11 Special rules for automobile liability insurance and no-fault automobile insurance.
- 220.12 [Reserved] organizations.
- 220.13 Special rules for workers' compensation programs.
- 220.14 Definitions.

**AUTHORITY:** 5 U.S.C. 301; 10 U.S.C. 1095.

**SOURCE:** 55 FR 21748, May 29, 1990, unless otherwise noted.

**§ 220.1 Purpose and applicability.**

(a) This part implements the provisions of 10 U.S.C. 1095, 1097b(b), and 1079b. In general, 10 U.S.C. 1095 establishes the statutory obligation of third party payers to reimburse the United States the reasonable charges of healthcare services provided by facilities of the Uniformed Services to covered beneficiaries who are also covered

by a third party payer's plan. Section 1097b(b) elaborates on the methods for computation of reasonable charges. Section 1079b addresses charges for civilian patients who are not normally beneficiaries of the Military Health System. This part establishes the Department of Defense interpretations and requirements applicable to all healthcare services subject to 10 U.S.C. 1095, 1097b(b), and 1079b.

(b) This part applies to all facilities of the Uniformed Services; the Department of Transportation administers this part with respect to facilities to the Coast Guard, not the Department of Defense.

(c) This part applies to pathology services provided by the Armed Forces Institute of Pathology. However, in lieu of the rules and procedures otherwise applicable under this part, the Assistant Secretary of Defense (Health Affairs) may establish special rules and procedures under the authority of 10 U.S.C. 176 and 177 in relation to cooperative enterprises between the Armed Forces Institute of Pathology and the American Registry of Pathology.

[67 FR 57740, Sept. 12, 2002]

#### § 220.2 Statutory obligation of third party payer to pay.

(a) *Basic rule.* Pursuant to 10 U.S.C. 1095(a)(1), a third party payer has an obligation to pay the United States the reasonable charges for healthcare services provided in or through any facility of the Uniformed Services to a covered beneficiary who is also a beneficiary under the third party payer's plan. The obligation to pay is to the extent that the beneficiary would be eligible to receive reimbursement or indemnification from the third party payer if the beneficiary were to incur the costs on the beneficiary's own behalf.

(b) *Application of cost shares.* If the third party payer's plan includes a requirement for a deductible or copayment by the beneficiary of the plan, then the amount the United States may collect from the third party payer is the reasonable charge for the care provided less the appropriate deductible or copayment amount.

(c) *Claim from United States exclusive.* The only way for a third party payer to satisfy its obligation under 10 U.S.C.

1095 is to pay the facility of the uniformed service or other authorized representative of the United States. Payment by a third party payer to the beneficiary does not satisfy 10 U.S.C. 1095.

(d) *Assignment of benefits or other submission by beneficiary not necessary.* The obligation of the third party payer to pay is not dependent upon the beneficiary executing an assignment of benefits to the United States. Nor is the obligation to pay dependent upon any other submission by the beneficiary to the third party payer, including any claim or appeal. In any case in which a facility of the Uniformed Services makes a claim, appeal, representation, or other filing under the authority of this part, any procedural requirement in any third party payer plan for the beneficiary of such plan to make the claim, appeal, representation, or other filing must be deemed to be satisfied. A copy of the completed and signed DoD insurance declaration form will be provided to payers upon request, in lieu of a claimant's statement or coordination of benefits form.

(e) *Preemption of conflicting State laws.* Any provision of a law or regulation of a State or political subdivision thereof that purports to establish any requirement on a third party payer that would have the effect of excluding from coverage or limiting payment, for any health care services for which payment by the third party payer under 10 U.S.C. 1095 or this part is required, is preempted by 10 U.S.C. 1095 and shall have no force or effect in connection with the third party payer's obligations under 10 U.S.C. 1095 or this part.

[55 FR 21748, May 29, 1990, as amended at 57 FR 41101, Sept. 9, 1992; 65 FR 7727, Feb. 16, 2000; 67 FR 57740, Sept. 12, 2002]

#### § 220.3 Exclusions impermissible.

(a) *Statutory requirement.* Under 10 U.S.C. 1095(b), no provision of any third party payer's plan having the effect of excluding from coverage or limiting payment for certain care if that care is provided in a facility of the uniformed services shall operate to prevent collection by the United States.

(b) *General rules.* Based on the statutory requirement, the following are general rules for the administration of 10 U.S.C. 1095 and this part.